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|------------------------------|--------------------------------------|-------------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/865,696 | <b>Applicant(s)</b><br>STRAWDER, GLENN G. |  |
|                              | <b>Examiner</b><br>RACHEL L. PORTER  | <b>Art Unit</b><br>3626                   |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 65-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 65-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                                    |
|------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                                  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                           |

## DETAILED ACTION

### *Notice to Applicant*

1. This communication is in response to the amendment filed 5/27/08. Claims 65-80 are pending.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 67-69, 76-77 and 80-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 67, it is unclear to the Examiner what additional steps are being performed and how claim 67 further limits claim 65. For example, the present claim recites "said computer compares ***an actual series of steps at least one step of said first series of steps*** of each said medical imaging machine with a predetermined series of steps and determines any difference between said predetermined series of steps and ***said actual series of steps at least one step of said second series of steps*** for each of said medical imaging machines." It is unclear whether the current language compares the predetermined steps with the steps actually performed, at least one step from the predetermined steps with at least one step from the steps actually performed, or if the applicant intended to claim another variant of currently recited language. For the purposes of applying art, the Examiner the examiner will interpret the current claim

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language to mean "comparing at least one step from the predetermined steps with at least one step from the steps actually performed."

Claim 68 recites the limitation "said computer means" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 65 does not recite computer means.

Regarding claim 69, it is unclear if the language of the claim, as presented is complete, since there is no "and" separating the final step from the rest of the claim. For the purpose of applying art, the Examiner will assume that the "and" has simply been omitted and that the comparing step is the final step of the claim.

Claim 76 recites the limitation "said memory" in line 6. There is insufficient antecedent basis for this limitation in the claim. The claim does not previously recite memory.

Regarding claim 77, is unclear what is included in the computer system and the functions performed by the recited components. For example claim 77 recites, "said computer ***storing a including means for storing*** at least two predetermined series of steps that an operator should perform when using said medical imaging machine to perform said medical function..." It is unclear if something has been omitted or this is merely a typographical error. However, a computer storing...including means for storing does not clarify the structure of the computer.

Claim 77 recites the limitation "said memory" in line 8. There is insufficient antecedent basis for this limitation in the claim. The claim does not previously recite memory.

Claims 80-82 inherit the deficiencies of claim 77 through dependency and are also rejected.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 65,67-69,71-73, and 76-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al (USPN 5,088,981) in view of Prince (US 5417213) [claim 65] Howson et al discloses an apparatus for monitoring the operations of an operator of a machine that performs a medical function, comprising:

- a computer for storing (col. 6, lines 27-36) a first series of steps (e.g. standard protocol of operations) that an operator should perform when using said machine to perform said medical function, (col. 6, lines 60-68; col. 12, lines 13-38)
- said computer also storing a second series of steps that set forth what the operator of said machine performed during the use of the machine to perform said medical function, (col. 8, lines 58-68; col. 12, lines 13-38)
- said computer including a program for comparing said first series of steps (standard protocol) with said second series of steps (col. 8, lines 58-68— monitoring compliance of patient with prescribed delivery schedule)

Howson discloses an apparatus as outlined above, but discloses that it is an infusion pump, not an imaging device. Prince discloses a system wherein the apparatus includes an infusion pump and a medical imaging device. (col. 12, lines 9-36) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Howson with the teaching of Prince to combine an infusion system with an MRI system (a machine which takes pictures of a part of the body.) As suggested by Prince, one would have been motivated to include this feature to facilitate proper or desired timing between the injection of the magnetic resonance agent and the acquisition of image data, in addition to providing proper rates of infusion of the contrast agent. (col. 12, lines 19-25).

[claim 67] Howson discloses the method as defined in claim 65, in which said computer compares an actual operation of each machine with a standard procedure and determines any difference or similarity between said standard procedure and said actual operation. (col. 8, lines 58-68)

[claim 68 ] Howson and Prince disclose the apparatus of claim 65 as explained in the rejection of claim 65. Howson also discloses providing a computer with a memory, (col. 6, lines 27-36) providing said memory with a standard protocol for operating said machine to perform a medical function, (col. 6, lines 60-68; col. 12, lines 13-38); and providing an operator for operating said machine. Howson does not expressly disclose a method in which there are a plurality of machines each of which perform a medical

function, plural operators for operating said machines, providing computer comparisons of said standard protocol with the operations of each operator. Furthermore, Howson does not disclose the step of providing at least one computer for each machine of the plurality of machines.

However, at the time of the applicant's invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of Howson to include a plurality of machines each of which perform a medical function, plural operators for operating said machines, providing computer comparisons of said standard protocol with the operations of each operator and providing at least one computer for each machine of the plurality of machines. (Multiplication or duplication of parts for multiple effects is an obvious modification over the prior art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8, 11; 549 F.2d 833 (7th Cir. 1977); *In re Harza*, 124 USPQ 378, 380; 274 F.2d 669 (CCPA 1960)) One would have been motivated to include this feature to increase the efficiency of the system, by allowing more than one operator to work at one time.

[claim 69] Howson discloses a method of monitoring the operations of an operator of a medical machine which gathers medical information about a patient, comprising:

- providing a computer with a memory, (col. 6, lines 27-36)
- storing in said computer a predetermined series of steps (e.g. standard protocol of operations) for operating said machine to perform a medical function, (col. 6, lines 60-68; col. 12, lines 13-38)

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- entering into said memory the actual series of steps of said operator in operating said machine, (col. 8, lines 58-68; col. 12, lines 13-38)
- comparing said predetermined series of steps with said actual series of steps by said operator. (col. 8, lines 58-68)

Howson discloses a method as outlined above, but discloses that it is an infusion pump, not an imaging device. Prince discloses a system and system wherein the apparatus includes an infusion pump and a medical imaging device. (col. 12, lines 9-36) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method and system of Howson with the teaching of Prince to combine an infusion system with an MRI system (a machine which takes pictures of a part of the body.) As suggested by Prince, one would have been motivated to include this feature to facilitate proper or desired timing between the injection of the magnetic resonance agent and the acquisition of image data, in addition to providing proper rates of infusion of the contrast agent. (col. 12, lines 19-25).

[claim 71,73 ] Howson discloses the method of claim 65 as explained in the rejection of claim 65. Howson also discloses providing a computer with a memory, (col. 6, lines 27-36) providing said memory with a standard protocol for operating said machine to perform a medical function, (col. 6, lines 60-68; col. 12, lines 13-38); providing an operator for operating said machine, (col. 8, lines 58-68; col. 12, lines 13-38) and providing comparisons by said computer which compare said standard protocol and said operations of said operator. (col. 8, lines 58-68).

Howson does not expressly disclose a method in which there are a plurality of machines each of which perform a medical function, plural operators for operating said machines, providing computer comparisons of said standard protocol with the operations of each operator. Furthermore, Howson does not disclose the step of providing at least one computer for each machine of the plurality of machines.

However, at the time of the applicant's invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of Howson to include a plurality of machines each of which perform a medical function, plural operators for operating said machines, providing computer comparisons of said standard protocol with the operations of each operator and providing at least one computer for each machine of the plurality of machines. (Multiplication or duplication of parts for multiple effects is an obvious modification over the prior art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8, 11; 549 F.2d 833 (7th Cir. 1977); *In re Harza*, 124 USPQ 378, 380; 274 F.2d 669 (CCPA 1960)) One would have been motivated to include this feature to increase the efficiency of the system, by allowing more than one operator to work at one time.

[claim 72] Howson discloses a method as defined in claim 65, in which said computer provides information on procedures performed on said machines as well as summaries of the operations of the machine. (col. 8, line 58-68; col. 12, lines 53-66) Howson does not expressly disclose that this step is performed for a plurality of computers or machines.

However, at the time of the applicant's invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of Howson to include a plurality of



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machines and a plurality of computer comparisons/ summaries for each machine and the operations performed on the machines. (Multiplication or duplication of parts for multiple effects is an obvious modification over the prior art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8, 11; 549 F.2d 833 (7th Cir. 1977); *In re Harza*, 124 USPQ 378, 380; 274 F.2d 669 (CCPA 1960)) One would have been motivated to include this feature to increase the efficiency of the system, by allowing more than one operator to work at one time.

[claim 76] Howson discloses the method of monitoring the work of an operator of a medical machine comprising:

- providing a medical machine which requires an operator to make a series of steps in order for such machine to produce desired results, (col. 6, lines 27-36; col. 8, lines 58-68; col. 15, line 58-col. 16, line 2))
- providing a computer means, (col. 6, lines 27-36)
- entering into a memory data which represents predetermined series of steps of said operator in operating during use of said machine with each such entry occurring prior to the next operation of said machine undertaken by said operator, and (col. 8, lines 58-68)
- entering into said computer means the actual series of steps of said operator in operating said machine, (col. 8, lines 58-68; col. 12, lines 13-38)
- comparing said entries into said computer means actual steps with said predetermined series of steps. (col. 8, lines 58-68; col. 12, lines 44-66)

Howson discloses a method as outlined above, but discloses that it is an infusion pump, not an imaging device. Prince discloses a system wherein the apparatus includes an infusion pump and a medical imaging device. (col. 12, lines 9-36) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method and system of Howson with the teaching of Prince to combine an infusion system with an MRI system (a machine which takes pictures of a part of the body.) As suggested by Prince, one would have been motivated to include this feature to facilitate proper or desired timing between the injection of the magnetic resonance agent and the acquisition of image data, in addition to providing proper rates of infusion of the contrast agent. (col. 12, lines 19-25).

[claim 77] The limitations of claim 77 are addressed by the rejection of claims 65 and 76 and incorporated herein.

[claims 78-79] Howson and Prince disclose the system of claim 65 as explained in the rejection of claim 65. Howson and Prince do not expressly disclose that medical imaging system include any radiology imaging machine. However, Prince does disclose that catheter-based radiology techniques (e.g. X-ray and CT) are well-known in the art. (col. 1, lines 20-28) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art try to monitor the administration of radiographic agents using the system and method of Howson. As indicated by Prince, the use of

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radiography yields high quality images, but can be risky if not properly handled. (col. 1, lines 20-40).

[claims 80-82] Howson and Prince disclose the system of claim 65 as explained in the rejection of claim 77. Howson and Prince do not expressly disclose that medical imaging system include any radiology imaging machine. However, Prince does disclose that catheter-based radiology techniques (e.g. X-ray and CT) are well-known in the art. (col. 1, lines 20-28) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art try to monitor the administration of radiographic agents using the system and method of Howson. As indicated by Prince, the use of radiography yields high quality images, but can be risky if not properly handled. (col. 1, lines 20-40).

6. Claims 66 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howson and Prince in view of Dorne (USPN 5,325,293).

[claim 66] Howson and Prince disclose the apparatus as defined in claim 65, as explained in the rejection of claim 65. However, Howson does not disclose an apparatus in which said computer has an output which sets forth prices computed from the operations performed by said machine.

Dorne discloses an apparatus in which a computer has an output which sets forth prices computed from the operations performed by said machine. (i.e. determining how many of a particular examination have been performed and determining how much

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money a particular number of examinations produce) (col. 9, lines 53-60; col. 15, lines 60-co1.16, line 19) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the apparatus of Howson and Prince in combination with the teaching of Dorne to provide output on the prices computed from operations performed by a machine. As suggested by Dorne, one would have been motivated to include this feature to provide physicians and medical personnel with billing information without requiring them to have a thorough understanding of the complex nomenclature used in the CPT coding system (col. 3, lines 1-15).

[claim 70] Howson and Prince disclose the apparatus as defined in claim 65, as explained in the rejection of claim 69. However, Howson does not disclose an apparatus in which said computer has an output which sets forth prices computed from the operations performed by said machine.

Dorne discloses an apparatus in which a computer has an output which sets forth prices computed from the operations performed by said machine. (i.e. determining how many of a particular examination have been performed and determining how much money a particular number of examinations produce) (col. 9, lines 53-60; col. 15, lines 60-co1.16, line 19) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the apparatus of Howson and Prince in combination with the teaching of Dorne to provide output on the prices computed from operations performed by a machine. As suggested by Dorne, one would have been motivated to include this feature to provide physicians and medical personnel with billing

information without requiring them to have a thorough understanding of the complex nomenclature used in the CPT coding system (col. 3, lines 1-15)

### ***Response to Arguments***

7. Applicant's arguments with respect to claims 65-80 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL L. PORTER whose telephone number is (571)272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, (Christopher) Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L. P./  
Examiner, Art Unit 3626

/C Luke Gilligan/  
Supervisory Patent Examiner, Art Unit 3626